K012209
p1 of 3



AUG 1 5 2001

# CAPIOX® SP Pump with X-Coating

**Submitter Information:**

Name and Address:
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton MD 21921

Contact Person: Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: June 29, 2001

**Device Names:**

Proprietary Name: CAPIOX® SP Pump with X-Coating
Product Code: CX*SP45X
Common Name: Cardiopumonary Bypass Centrifugal Pump
Classification Name: Non-Roller Type CPB Blood Pump

**Predicate Device:**

Terumo Cardiovascular Systems Corporation has identified the uncoated CAPIOX® SP Pump, Product Code CX*SP45, as the predicate device for the determination of substantial equivalence. The predicate device is cleared with Premarket Notification K962981.

**Intended Use:**

The CAPIOX® SP Pump with X-Coating is used to facilitate blood flow in the extracorporeal circuit for circulatory support during extracorporeal circulation for up to 6 hours.

**Principles of Operation and Technology:**

The CAPIOX® SP Pump with X-Coating performs its function using centrifugal force technology. As blood enters the device via the blood inlet port, centrifugal forces created by the pump activity will propel the blood through the pump head and out of the device via a blood outlet port.

**Design and Materials:**

The design of the CAPIOX® SP Pump with X-Coating is such that the device meets its stated intended use, and provides an acceptable level of performance and safety to the patient.

The device is a hardshell housing that contains a blood compartment and a non-blood compartment. Within the blood compartment is a rotating mechanism that imparts centrifugal force upon blood as it enters the device. The centrifugal force moves the blood out of the device via the outlet port.

The non-blood compartment is designed to magnetically couple with a pump console so that it can be electrically driven by the console.

The materials of construction for the CAPIOX® SP Pump with X-Coating are the exact same materials that are used in the predicate uncoated CAPIOX® SP Pump – except for the addition of X-coating to the subject device. The differences in the materials do not raise any new issues of safety or effectiveness of the device.

**Performance:**
Terumo Cardiovascular Systems Corporation conducted performance evaluations of the CAPIOX® SP Pump with X-Coating to demonstrate its equivalence to the uncoated CAPIOX® SP Pump. The following performance tests were conducted:

- Long Duration (9-hour) Circulation Evaluation
- Priming Volume
- Air Handling Efficiency
- Hemolytic Effects of the Device Upon Cellular Blood Components
- Evaluation for Heat Generation
- Mechanical Integrity
- Strength of Tubing Connection

**Substantial Equivalence Comparison:**
The CAPIOX® SP Pump with X-Coating is substantially equivalent to the uncoated CAPIOX® SP Pump:

- Intended Use: Both the CAPIOX® SP Pump with X-Coating and the predicate CAPIOX® SP Pump are intended to facilitate blood flow in the extracorporeal circuit for circulatory support during extracorporeal circulation for up to 6 hours.

- Principles of Operation and Technology: The CAPIOX® SP Pump with X-Coating and the predicate SP Pump each utilize the same technologies in the operation of the devices. As blood enters the device via the blood inlet port, centrifugal forces created by the pump activity will propel the blood through the pump head and out of the device via a blood outlet port.

- Design and Materials: The CAPIOX® SP Pump with X-Coating and the predicate SP Pump each have the same identical design. Each device is a hardshell housing that contains a blood compartment and a non-blood compartment. Within the blood

compartment is a rotating mechanism that imparts centrifugal force upon blood as it enters the device. The centrifugal force moves the blood out of the device via the outlet port.

The non-blood compartment is designed to magnetically couple with a pump console so that it can be electrically driven by the console.

The materials of construction for the CAPIOX® SP Pump with X-Coating are the exact same materials that are used in the predicate uncoated CAPIOX® SP Pump – except for the addition of X-coating to the subject device.

- Performance: Comparisons between the performance of the CAPIOX® SP Pump with X-Coating and the predicate SP Pump were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the two devices.

**Substantial Equivalence Summary:**
In summary, the CAPIOX® SP Pump with X-Coating and the uncoated CAPIOX® SP Pump are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

**Additional Safety Information:**
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo Cardiovascular Systems Corporation conducted the biocompatibility studies recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

**Conclusion:**
In summary, the CAPIOX® SP Pump with X-Coating is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated CAPIOX® SP Pump (K962981).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2001

Mr. Gary A. Courtney, RAC
Regulatory Affairs Specialist
Terumo Cardiovascular System Corporation
126 Blue Ball Road
Elkton, MD 21921

Re: K012209
CAPIOX® SP Pump with X-Coating
Regulation Number: 870.4360
Regulatory Class: III (three)
Product Code: KFM
Dated: July 13, 2001
Received: July 16, 2001

Dear Mr. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):**

**Device Name:** **CAPIOX® SP Pump with X-Coating (CX*SP45X)**

**Indications For Use:**

The CAPIOX® SP Pump with X-Coating is used to facilitate blood flow in the extracorporeal circuit for circulatory support during extracorporeal circulation for up to 6 hours.

The pump is a non-roller type pump and is a sterile device for single use only. The pump couples magnetically to, and is electrically driven by BioMedicus BioConsole Models 540 and 550 via the SP Pump Head adaptor.

A biocompatible coating, polymethoxyethylacrylate (PMEA), is intended to reduce the adhesion of platelets to the blood-contacting surfaces of the device.

Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012209

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)